

## REMARKS

Claims 56-58, 61-65, 67-76, and 78-81 are pending in the application. Claims 78-81 are added, claims 56, 57, 62-64, 71, 73 and 75 are amended, and claims 59, 60 and 77 are canceled. Claims 56, 71 and 78 are independent. Support for the new claims can be found, for example, on page 10, lines 7-25, Example 2. No new matter has been added. Amendments to claims 57, 62, 63, 64, 73 and 75 serve to broaden, rather than narrow them. Support for these amendments can be found throughout the specification. No new matter has been added. Reconsideration is respectfully requested in light of the foregoing amendments and the remarks that follow.

### I. REJECTION UNDER 35 U.S.C. §112

In paragraph 2 on page 3 of the Office Action, claims 56-65 and 67-77 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 56, the examiner notes that the phrase “including” in lines 3 and 5 of the claim renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Regarding claim 61, the examiner also notes that the phrase “includes” in line 2 of the claim, renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Regarding claim 71, the examiner again notes that the phrase “including” in lines 3 and 5 of the claim, renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Lastly, regarding claim 73, the examiner further notes that the phrase “includes” in lines 2 and 4 of the claim, renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. .” To support the rejection, the Office Action cited M.P.E.P. § 2173.05(d).

The applicant respectfully traverses this rejection. It is clear that “including” and “includes” mean that what follows these words is part of the “composition,” “mixture,” or “gel” recited in the claims. Indeed, there seems to be no other way of interpreting “including” and “includes,” given that the dictionary defines “include” as “place, list, or rate as a part or component of a whole or of a larger group, class, or aggregate.” *Webster’s Third New International Dictionary, Unabridged*, Merriam-Webster, 2002, <http://unabridged.merriam-webster.com> (September 11, 2006). In addition, M.P.E.P. § 2111.03 notes that “including” or “includes” is synonymous with “comprising” or “comprises”, a transitional term regularly used in claim drafting.

It is respectfully submitted that M.P.E.P. § 2173.05(d) is not applicable in the present situation. That section of the M.P.E.P. points out that claims that recite elements as merely being exemplary of components that could be part of the invention (as evidenced by phrases like “for example” or “such as”) do not positively recite those elements and are indefinite under 35 U.S.C. § 112, second paragraph. However, the words “including” and “includes” have long been deemed appropriate claim terminology for reciting the elements of an invention, and the applicant accordingly requests withdrawal of this rejection. Reconsideration is respectfully requested.

## II. REJECTION UNDER 35 U.S.C. §103(a)

In paragraph 2 on page 4 of the Office Action, claims 56-65 and 67-77 are rejected under 35 U.S.C. §103(a) as being unpatentable over Schaffer U.S. Patent No. 4,528,180 and Winston U.S. Patent No. 4,891,211.

The examiner notes that Schaffer teaches a multi compartment vessel having flexible side walls comprising a first component containing a gel of hydrogen peroxide and a second chamber with an alkaline pH adjusting agent (triethanolamine) (see abstract) and wherein upon squeezing the container (in response to applied pressure on the vessel), controlled quantities of each chamber are released (column 2, line 18-26).

CARBOPOL (high molecular weight cross-linked polyacrylic acid) is incorporated as a thickener (see column 4, example 1). The pH is adjusted to between 3 and 6 which overlaps and encompasses the claimed pH greater than 5.5 (column 3, lines 24-26). A stabilizer is disclosed (see abstract). It teaches the pH adjusting agent, triethanolamine (column 3, line 24). The amount of water in the examples is about 89% (see the examples), which meets the limitations of claim 61 (at least 70% water by weight of the mixture). Both chambers of Schaffer contain compositions in the form of gels (column 3, line 18) or pastes (column 3, lines 46-47).

However, the examiner also admits that Schaffer differs in that it does not teach the same stabilizing agents as in instant claim 63, but that it is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In Re Font*, 213 USPQ 532. Thus, the examiner contends that it would have been made obvious to one of ordinary skill in art at the time it was made to substitute the stabilizers instantly recited in claim 63 for the stabilizers recited in Schaeffer and that such a modification would have been motivated by the reasoned expectation of producing a stabilized dentifrice in a dosage delivery unit.

Regarding claims 67-69, drawn to a pH of the mixture, the examiner notes that it appears that Schaffer would adjust pH of the mixture since the pH of the first compartment is between 3 and 6 and the second compartment is sodium bicarbonate, which is alkaline. Thus, when the two components are mixed, there would result an alkaline pH. The examiner also admits that the rejection is under 103(a) regarding these claims since the final pH is not recited in Schaffer; however, the examiner contends that a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the properties applicant discloses and/or claims (i.e. a pH of 3 or 6 mixing with

an alkaline sodium bicarbonate) are necessarily present, and it would have been made obvious to one of ordinary skill in art at the time it was made to employ an alkaline pH in a dosage delivery unit for delivering a tooth bleaching mixture motivated by the teaching of Schaffer who employs a first composition of hydrogen peroxide gel with a pH of 3 to 6 and a sodium peroxide paste, which is alkaline which would result in an alkaline tooth whitening mixture.

The examiner also cites Winston to teach sodium percarbonate as a hydrogen peroxide releasing agent (precursor) employed in a dentifrice. Thus, the examiner notes that it is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In Re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. It would have been made obvious to one of ordinary skill in art at the time it was made to employ sodium percarbonate in a container with a dentifrice motivated by the teaching of Winston that sodium percarbonate is a safe and palatable hydrogen peroxide releasing agent (column 3, line 30-33).

Applicant respectfully traverses the rejection.

Schaeffer discloses a 2-component tooth paste or dentifrice in "a combination of a collapsible tube article having flexible side walls and a composition consisting of a gel component and a paste component and contained in said article, said combination being suitable for use in combating gum disease," with the first compartment containing a gel having "(i) 1-10% by volume of hydrogen peroxide, (ii) 0.05-1.2% by volume of a water dispersible copolymer of acrylic acid cross-linked with polyallyl sucrose; (iii) 0.1-1.5% by volume of a non-ionic cellulose gum stabilizer (iv) purified water and (iv) a neutralizing agent selected from the group consisting of sodium hydroxide, potassium hydroxide, triethanolamine, diisopropylamine and ammonia in

an amount sufficient to raise the pH of said gel to within about 3-6 said first compartment having an orifice for dispensing controlled amounts of said gel upon squeezing of said flexible sidewalls;" and a second compartment containing a paste having "(i) 10-50% by weight of sodium bicarbonate; (ii) 1-6% by weight of a salt selected from the group consisting of NaCl and MgSO.sub.4 ; (iii) 1-3% by weight of a thickener-stabilizer selected from the group consisting of cellulose gum magnesium aluminum silicate, and mixtures thereof; (iv) 5-30% by weight of a humectant selected from the group consisting of glycerin, sorbitol, polyethylene glycol and polypropylene glycol, (v) purified water and (vi) 1-40% by weight of a cleaning-polishing agent selected from the group consisting of CaSO.sub.4, Ca.sub.3 (PO.sub.4).sub.2 and hydrated aluminum oxide, and (viii) 0.1-2.5% by weight of sodium lauryl sulfate." See abstract.

Winston discloses a one-component toothpaste or gel dentifrice, "comprising a mixture of up to about 70% sodium bicarbonate with about 1 to 10% sodium percarbonate, in a carrier which is substantially free of glycerin and which comprises about 20 to 75% of a polyethylene glycol humectant. Dentifrices prepared in accordance therewith provide a pre-mixed, stable combination of sodium bicarbonate and peroxide-releasing agent in a palatable and convenient form." See Col. 2, lines 60-65.

The compositions recited in both of independent claims 56 and 71 include a chelating agent. (This feature is supported, for example, at page 10, lines 12-13, of the application.) The application discusses the advantages of including a chelating agent at page 6, lines 8-18. The applicants do not find a chelating agent in any of the formulations disclosed in Schaeffer and Winston, nor does it appear that either reference discusses any advantages of using a chelating agent in a tooth bleaching mixture.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in

the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicant respectfully submits that there is no teaching or motivation to combine the 2 cited references, one disclosing a 2-component toothpaste and the other one disclosing a 1-component toothpaste, to arrive at the inventions of claims 56 and 71. Therefore, independent claims 56 and 71 are patentable over Schaeffer and Wilson.

Claims 57-58, 61-65, 67-70, and 72-76 are dependent from claims 56 and 71 respectively and are being rejected under 35 U.S.C. §103(a) as being unpatentable over Schaffer U.S. Patent No. 4,528,180 and Winston U.S. Patent No. 4,891,211. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that this rejection is moot in view of the remarks made in connection with independent claims 56 and 71 above. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish them from the cited references. Therefore, dependent claims 57-58, 61-65, 67-70, and 72-76 are also in condition for allowance.

Applicants respectfully request that the rejection of claims 56-58, 61-65, and 67-77 under 35 U.S.C. §103(a) as being unpatentable over Schaffer U.S. Patent No. 4,528,180 and Winston U.S. Patent No. 4,891,211 be withdrawn. Reconsideration is respectfully requested.

### III. NEW CLAIMS

New independent claim 78 is based closely on previous claim 56, with the added feature that the composition in the first chamber is alkaline. This feature is supported at page 10, lines 7-25, where it is disclosed that the part B composition has a pH of 7.0,

while the mixture of the parts A and B compositions has a pH of 9.0, so that the part A hydrogen-peroxide-containing composition is alkaline (with a pH above 9.0).

The applicant respectfully submits that claim 78 is patentable over Schaeffer and Wilson. All of Schaeffer's compositions containing hydrogen peroxide (Examples 1-6) have a pH less than 4.5. As for Wilson, the applicant does not find any disclosure concerning the pH of the compositions discussed in it.

Since independent claim 78 is patentable, its dependent claims 79-81 are likewise patentable. Favorable action is respectfully requested.

#### IV. INFORMATION DISCLOSURE STATEMENT

The Office Action indicates that copies of several documents cited in the Information Disclosure Statement of November 2, 2004, were not received by the Patent and Trademark Office. The documents were not considered by the Examiner and for that reason are now relisted on the attached Form PTO/SB/08A. The Examiner is respectfully requested to consider these documents and to return the form indicating that she has done so.

The applicant believes that no fee is required for this Information Disclosure Statement, but any such fee may be charged to Deposit Account No. 50-3717.

#### V. PETITION TO WITHDRAW TERMINAL DISCLAIMER

This Office Action withdrew the double patenting rejection based on application 10/050,196, now U.S. Patent 5,958,144.

The applicant requests that this paper be considered a petition under 37 C.F.R. § 1.182 for withdrawal of the July 21, 2005, Terminal Disclaimer with respect to that application. See M.P.E.P. § 1490 VII.A. Applicant requests that the \$400 fee under 37 C.F.R. § 1.17(f) be charged to Deposit Account 50-3717 and the fee transmittal form is enclosed. Favorable action is respectfully requested.

VI. CONCLUSION

The applicant believes that this Amendment addresses all of the points raised in the Office Action, and requests reconsideration and allowance of the present application, with pending claims 56-58, 61-65, 67-76, and 78-81.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8501.

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Respectfully submitted,



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